

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 11, 17, 19, 20 and 27 have been amended. In particular, to clarify applicants' invention, independent claims 11, 17 and 27 have been amended to recite that the "lipid is obtained by" Further, independent claims 17 and 27 have been amended to recite "arachidonic acid to the total fatty acid[s]" Additionally, independent claim 17 has been amended to clarify applicants' invention by reciting "[a]n isolated arachidonic acid-containing lipid . . ." and to correct a grammatical error. Finally, claims 19 and 20 have been amended to delete dependence on canceled claim 18 and to revise the preamble so as to be consistent with "standard" dependent claim language. None of these amendments are intended to limit the scope of the claims or any element(s) recited therein. Support for all of the present amendments can be found throughout the originally filed application. Accordingly, no new matter has been added.

Turning now to the Official Action, the Examiner has noted that claims 11, 17, 19-20, and 27-37 have been considered on the merits.¹ The Examiner has further noted that,

¹ Claims 1-10, 13-16 and 23-26 have properly been noted by the Examiner as being withdrawn from consideration as directed to a non-elected invention. The Examiner further properly noted that claims 12, 18, 21 and 22 have been canceled. Applicants note the inconsistency with regard to the status of claim 21 in the Amendment and Reply filed on January 27, 2003, and hereby confirm that claim 21 should have been indicated as being canceled and not amended.

to conform to standard practice, independent claims should begin with the term "The" and dependent claims should start with "A" or "An."² As discussed above, dependent claims 19 and 20 have been amended to begin with the term "The."

Claims 11, 17, 19-20 and 27-37 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for purportedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is respectfully traversed.

The Examiner has indicated that claims 11 and 27 are confusing since they use different terminology to refer to the percentage of arachidonic acid in the total fatty acid(s) in the lipid. So as to be consistent, and not to limit the scope of either claim or any element(s) recited therein, claims 17 and 27 have been amended to recite "arachidonic acid to the total fatty acid[s]" This language is consistent with the language in claim 11, not to mention the manner in which such phraseology is used later in such claims when discussing the percentage of eicosapentaenoic acid "to" total fatty acids. Support for this amendment can be found in the originally-filed application in at least original claim 11.

The Examiner has further stated that claims 11, 17 and 27 are vague and indefinite for recitation of the term "obtainable." To clarify applicants' invention and not to acquiesce to the Examiner's rejection, claims 11, 17 and 27 have been amended to recite the

² Despite the Official Action stating the reverse, the standard practice was confirmed with the Examiner during a telephone call on December 9, 2003.

term "obtained." Once again, this amendment is not intended to limit the scope of the claims or any element recited therein.

In view of the above, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Claims 11-12, 17-22 and 27-37 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Totani et al., IND. APPL. SINGLE CELL OILS, Ed. Kyle et al., American Oil Chemists Society, Champaign, Illinois, pp. 52-60 (1992) ("Totani"). This rejection is respectfully traversed.

Initially, it is noted that claim 12 was previously canceled. Thus, the rejection should be inapplicable to claim 12. As to currently pending claims, 11, 17, 19-20 and 27-37, applicants respectfully submit that Totani fails to teach or suggest each element of the claimed invention.

Independent claim 11, for instance, states that the arachidonic acid-containing microbial lipid contains "72% by weight or more of arachidonic acid to the total fatty acids" in the lipid. Totani, on the other hand, refers to a lipid having less than the amount claimed by applicant. More specifically, Totani refers in the abstract to a lipid having an arachidonic acid content of 71.2% — not 72 % as stated in claim 11. Thus, Totani cannot anticipate claim 11 of the present application.

In the Official Action, the Examiner has stated that the lipid of Totani "has been purified to contain 99% arachidonic acid." Official Action at 3 (citing page 59, paragraph

2 of Totani). However, the purified arachidonic acid referenced on page 59 of Totani is different from the "isolated arachidonic acid-containing microbial lipid" as claimed in the present invention. Page 59 of Totani describes that the arachidonic acid was concentrated by a "urea adduct separation process which removed (as adducts) the shorter chain and less saturated fatty acids." In this stage (after urea adduct separation), the fatty acids are in the form of free acid and not in the form of triglyceride in which the microbial lipids are produced originally. Free fatty acid mixtures are not edible, whereas the lipid of the claimed invention (which is in the form of mainly triglyceride) is an edible composition. Thus, the purified arachidonic acid referenced on page 59 of Totani is different from the claimed invention.

Moreover, there is no motivation or suggestion in Totani to extract microbial cells with an organic solvent so as to obtain a microbial lipid which contains 72% by weight or more of arachidonic acid to the total fatty acids in the lipid and contains 0.5% by weight or less of eicosapentaenoic acid. In fact, Totani fails to even mention the eicosapentaenoic acid content of its lipid. Hence, Totani cannot render claim 11 of the present invention obvious.

As to independent claims 17 and 27, Totani fails to anticipate or render obvious such claims as Totani fails to teach or suggest a lipid obtained by culturing a microorganism in which ω 3 desaturase activity has been decreased or is lacking. The Examiner has stated, citing *In re Thorpe*, 227 U.S.P.Q. 964 (Fed. Cir. 1985), that the patentability of product-by-process claims are based upon the product itself. However,

product-by-process claims must be analyzed to determine what effect, if any, the recited process of preparation has on the structure, composition or properties of the claimed product. M.P.E.P. § 2113. Here, the recited process of preparation is a positive step which results in a lipid that contains both a high ratio of arachidonic acid and a low content of eicosapentaenoic acid. Totani fails to teach or suggest a lipid with this type of arachidonic acid and eicosapentaenoic acid ratio. Accordingly, claims 17 and 27 cannot be anticipated or rendered obvious by Totani

A dependent claim includes all of the limitations of the independent claims from which it ultimately depends. Since Totani fails to teach or suggest every element of the independent claims, Totani necessarily fails to anticipate or render obvious those dependent claims which include all of the limitations of the independent claims from which they, either directly or indirectly, depend.

In view of the above, the Examiner is respectfully requested to withdraw the rejection over Totani.

Claims 11-12, 17-22 and 27-37 have further been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 25 U.S.C. § 103(a) as allegedly being obvious over Li et al., THE CANADIAN JOURNAL OF CHEMICAL ENGINEERING, 73:135-139 (1995) ("Li"). This rejection is also respectfully traversed.

As with the Totani reference discussed above, Li fails to teach or suggest every element of currently pending claims 11, 17, 19-20 and 27-37.³ Citing page 138, first full paragraph and Table 6 of Li, the Examiner has stated that Li teaches a "lipid from *Mortierella* [that] contains 72.5% arachidonic acid." Official Action at 4. However, a close examination of this portion of the Li reference reveals that Li fails to teach or suggest applicants' claimed invention.

In Table 6 of the Li reference (the row in which 72.50 % arachidonic acid is set forth), a fatty acid composition of crude lipid extract was shown as 34.23%. However, what is named in the Li reference as the "Arachidonic acid concentrate (%)" in Table 6 was made by urea treatment after saponification. Using the saponification process as described in the Li reference, free fatty acids were obtained (see lines 5-7 of first full paragraph in column 1 of page 138). Then, as in Table 6, using urea, urea adduct of poly-unsaturated fatty acids was produced (see lines 7-11 of first full paragraph in column 1 of page 138).⁴

³ As mentioned above, claim 12 was previously canceled. Thus, the Official Action should not have included claim 12 in the rejection.

⁴ It is noted that the urea adduct is generally made with free poly-unsaturated fatty acids, not with free saturated fatty acids nor with free mono-unsaturated fatty acids. It can be confirmed from Table 6 of Li that the urea adduct was made with free poly-unsaturated fatty acids since the concentrates for all the free saturated fatty acids and mono-unsaturated fatty acids are closer, nearly to zero.

As for the case of palmitic acid (16:0), the concentration of crude lipid extract was 14.25% but the concentration of free acid was reduced to 0.04%, and as for the case of stearic acid (18:0), the concentration of crude lipid extract was 16.57% whereas the concentration of free acid was reduced to 0.06%. As for arachidonic acid (20:4), the content in the crude lipid extract was 34.23% and it was increased to 72.5% as in the form of free acid obtained by extraction after recovery of urea adduct after saponification.

Thus, the arachidonic acid concentrate of 72.5% obtained and shown in Table 6 is not an "isolated arachidonic acid-containing microbial lipid" as claimed but rather a free arachidonic acid mixture recovered from the urea adduct concentrated by urea inclusion. As described above with regard to the Totani reference, the fatty acid in the free form as described in Li differs from the claimed lipid at least in that fatty acid in free form is not edible, whereas the claimed lipid is edible.

Since Li fails to teach an arachidonic acid-containing microbial lipid that contains 72% by weight or more of arachidonic acid in the total fatty acids in the lipid, Li fails to anticipate the claimed invention.

Further, there is no motivation or suggestion in Li to extract microbial cells with an organic solvent so as to obtain a microbial lipid which contains 72% by weight or more of arachidonic acid in the total fatty acids in the lipid and contains 0.5% by weight or less of eicosapentaenoic acid. Therefore, Totani cannot render claim 11 of the present invention obvious.

As with the Totani reference, Li fails to anticipate or render obvious independent claims 17 and 27 for failing to teach or suggest a lipid obtained by culturing a microorganism in which ω 3 desaturase activity has been decreased or is lacking.

For the same reasons as discussed above concerning the Totani reference, the dependent claims can be anticipated or rendered obvious by Li.

In view of the above, the Examiner is respectfully requested to withdraw the rejection over Li.

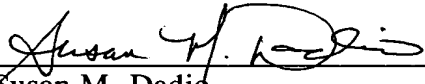
From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this Amendment and Reply or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: December 10, 2003

By: 
Susan M. Dadio
Registration No. 40,373

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620